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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,953	02/22/2002	William J. Hennen	4428.2US	6427

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TRASK BRITT  
P.O. BOX 2550  
SALT LAKE CITY, UT 84110

EXAMINER
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BROWN, STACY S

ART UNIT	PAPER NUMBER
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1648

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DATE MAILED: 05/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/081,953

Applicant(s)

HENNEN ET AL.

Examiner

Stacy S Brown

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-6, 13, 14, 16, 17 and 19-21 is/are ~~allowed~~ free of the prior art. *sn 5/2/03*
- 6) ☒ Claim(s) 7-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1. 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicant's preliminary amendment filed May 14, 2002 is acknowledged and entered.

Claims 1-21 are pending and examined.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-10 are rejected under 35 U.S.C. 112, first paragraph. The specification is enabling for preventing animals from exhibiting disease states associated with infection by some pathogens, such as those listed in claim 14. However, it does not reasonably provide enablement for any pathogen. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make of use the invention commensurate in scope with these claims.

a) The breadth of the claims is unreasonable, encompassing the prevention of any disease caused by a pathogen. The nature of the invention is drawn to eliciting an immune response to an antigen by administering transfer factor. The specification is not enabled for preventing disease associated with any type of pathogen. For example, HIV infection to date is not preventable. Applicant has enabled for eliciting a T-cell response, but not preventing HIV infection. The specification provides no guidance or examples of preventing HIV infection with their transfer factor composition. While Akari *et al* (*Vaccine*, 1997) and Bende *et al* (*AIDScience*, 2001) offer hope for passive vaccines, the unpredictability of the art shows that

Art Unit: 1648

vaccines for HIV for research animals to date have failed, as evidenced by Barouch *et al* (*Nature*, 2002). Barouch teaches that a single nucleotide mutation within an immunodominant Gag CTL epitope resulted in death from AIDS-related complication in a rhesus monkey (abstract).

b) The specification is not enabled for eliciting an immune response against a pathogen that was not the antigenic agent exposed to the source animal (in particular, claim 7). One of skill would not expect transfer factor to elicit an immune response against an antigen that the transfer factor is not specific for. There is no guidance or working examples of such as method in the specification. Applicant is enabled for eliciting an immune response against a pathogen that was the antigenic agent exposed to the source animal.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite “wherein said administering comprising preventing” or “treating”. It is unclear how the step of administering is also the step of preventing or treating. Administering is administering. Preventing or treating is an outcome of the method. Methods that lead to treatment should have endpoints that indicate that treatment has been achieved.

### ***Conclusion***

4. The claims are free of the prior art of record.

Art Unit: 1648

The prior art made of record by not relied upon is Tokoro (5,080,895). Tokoro teaches a method of eliciting an immune response by administering a transfer factor-like component. The transfer factor-like component is produced from eggs of a hen that has been immunized against an antigen. The transfer factor-like component is recovered from a fraction of at most 10,000 in molecular weight (abstract).

The claims are drawn to a method for eliciting a T-cell mediated immune response in an animal, comprising administering transfer factor. The transfer factor is generated by a non-mammalian source animal's egg in response to a T-cell mediated immune response to an antigenic agent. The transfer factor molecules have molecular weights of about 4000-5000 Daltons.

In the Declaration of William J. Hennen, Ph.D., submitted December 5, 2001 in parent application USSN 09/667,147 (now patent 6,468,543), Dr. Hennen elaborates on the meaning of the "transfer factor-like component" disclosed in Tokoro (paragraph 13 of the declaration). One of the references cited by Tokoro provides the background of the term "transfer factor-like component". The Dunnick reference referred to by Tokoro concludes that "no direct relationship has been established between TFLA (transfer factor-like activity) and in vivo transfers of cellular immunity". Further, Dr. Hennen says that the antigen used by Tokoro to immunize the hens would not have resulted in a T-cell mediated immune response, merely a B-cell response to ETEC (paragraph 21 of the declaration).

Therefore, given the teachings of Tokoro and the Hennen declaration of record in the parent application USSN 09/667,147, the instant method of eliciting a T-cell mediated immune

Art Unit: 1648


response to transfer factor (generated from hens' eggs immunized with antigen resulting in a T-cell mediated immune response) is not taught or suggested by the prior art of record.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday and alternate Wednesdays from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SSB

Stacy S. Brown  
May 2, 2003

  
JAMES HOUSEL 5/4/03  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600